Notice of Allowability	Application No.	Applicant(s)	
	10/518,654	BROOK ET AL.	
	Examiner	Art Unit	
	Andrew B. Freistein	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment filed 1/30/07*.

2. ☒ The allowed claim(s) is/are *1-5, 20, 24 and 28 (now 1-8)*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 1/30/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

The amendment filed 1/30/2007 was entered. Claims 1-31 are pending.

Information Disclosure Statement

Applicant's information disclosure statement (IDS), filed on 1/30/2007, has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Restriction Requirement

The restriction requirement between Group I (claims 1-5 and 20) and Group VI (claims 24 and 28) is withdrawn. The restriction requirement between the other groups is maintained. Applicant reserves the right to file one or more divisional applications on non-elected subject matter.

Claim Rejections - 35 USC § 103

Claims 1-5 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedemann et al., US 4,503,067 and Hildesheim et al., US 7,056,942. Applicant's arguments are deemed persuasive and the rejection is withdrawn.

Double Patenting

Claims 1 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 34 of copending Application No. 10/997,230. As a result of the amendment filed 1/30/2007 to the copending application, the rejection is withdrawn.

Claim Rejections - 35 USC § 112, 1st Paragraph

Claims 1-5 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As a result of the amendment filed 1/30/2007, the rejection is withdrawn.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given during a telephone interview with Attorney Grace Hsu on March 7, 2007.

This application has been amended as follows:

1. Cancel claims 6-19, 21-23, 25-27 and 29-31.

2. In the Specification, after the "title" and before the "Field of Invention", delete the sentence, "This application claims the benefit of U.S. Provisional Application No. 60/392,175, filed June 27, 2002." , and insert the sentence:

--This application is a National filing under 35 USC 371 of PCT/US03/20408, filed June 27, 2003, which claims the benefit of U.S. Provisional Application No. 60/392,175, filed June 27, 2002.--.

Reasons For Allowance

The instant invention is a compound, which is a crystalline carvedilol dihydrogen phosphate hemihydrate, a pharmaceutical composition comprising the compound and a

method of treating hypertension, congestive heart failure or angina comprising administering the compound or pharmaceutical composition containing the compound.

The closest relevant art is Hildesheim et al., US 7,056,942, which discloses a crystalline carvedilol hydrochloride hydrate. There is nothing in the prior art to suggest to a skilled artisan to produce a (1) phosphate salt and (2) a hemihydrate. The prior art is limited to the hydrochloride hydrate salt form.

Carvedilol is a well-known FDA-approved pharmacetical used in combination with other medications to treat heart failure, high blood pressure and angina (see MedlinePlus, Carvedilol, 2007, available at: http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a697042.html).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Andrew B. Freistein
Patent Examiner, AU 1626

for Joseph K. McKane
Supervisory Patent Examiner, AU 1626
Date: March 7, 2007